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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,123	02/18/2004	Mark W. Kroll	A04P1016US01	5391

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PACESETTER, INC.
15900 VALLEY VIEW COURT
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EXAMINER	
BERTRAM, ERIC D	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,123	KROLL, MARK W.	
	Examiner	Art Unit	
	Eric D. Bertram	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-20 and 22-25 have been considered but are moot in view of the new ground(s) of rejection, necessitated by applicant's amendment.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

3. The duty to disclose statement should read "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

4. The applicant's arguments that the current statement should be accepted are not found persuasive. As applicant pointed out, the rule was changed and published at 1135 OG 13 on Feb. 4, 1992 (Exhibit B) so that the "material to patentability" language was required. However, Exhibit C was submitted stating that forms that were "currently in use" in Feb. 1992 would still be valid. However, the current application was filed on 12/01/2004, and were not "in use" when 1135 OG 17 was published. Furthermore, "material to the examination" differs greatly from "material to patentability" because "material to patentability" encompasses a continuing duty to disclose information to the

office even after the examination process has concluded and the application has become a patent. Finally, MPEP 602.03 states that the "Duty to Disclose" statement must recite the "material to patentability" language. A new oath or declaration is still required.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 9/6/07 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-20 and 22-25 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 11, 13-20

and 23-25 of copending Application No. 10/782,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both describe methods and apparatuses for recording diagnostic data in temporary and long-term memory in an implantable device based on the detection of predetermined triggers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-6, 9, 10, 12-14 and 22-25 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Lade (US 2003/0144595). Lade discloses an implantable medical device (IMD) operative to monitor cardiac rhythm (see abstract).

10. Regarding claims 1, 3, 6, 12, 13 and 22-25 Lade discloses that the IMD monitors heart rate and other signals until a storage triggering event is detected (par. 0056 and 0057). The data is then stored in a temporary memory 94 (par. 0056) until the data may be downloaded to a long term memory and the temporary memory is cleared (par.

0040). Lade further discloses that the triggers are indicative of a cardiac arrhythmia that is impending and has yet to occur (par. 0050, 0056 and 0060). Lade also discloses that recording triggers are modified in order to customize the operation to suit the needs of a particular patient (par. 0040).

11. Regarding claim 2, Lade discloses the recording of intracardiac electrograms and event records (par. 0084).

12. Regarding claims 4, 5 and 14, the heart rate is monitored as a trigger parameter. For example, in order to determine if the heart rate increases or decreases, as shown in table 1, the current heart rate must be compared to a previous heart rate, which is considered to be a threshold value. If the heart rate is found to have increased, then the previous heart beat can be considered a "fast beat threshold value." Furthermore, an increase in heart rate inherently relates to a change in morphology.

13. Regarding claims 9 and 10, if the triggers indicate an arrhythmia is impending, then this is inherently a period of time with an elevated risk of arrhythmia, and Lade discloses that data will be recorded during this time period.

14. Regarding claim 22, Lade discloses that the suspected arrhythmia is confirmed prior to transferring data (par. 0058).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 7, 8 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lade in view of Legal Precedent. Lade, as described above, discloses the applicant's basic invention with the exception of specifically disclosing reviewing the data in order to determine if the triggers were correctly set to record important diagnostic data. However, Lade does disclose that the practitioner reviews the data recorded during follow-up visits in order to appraise the performance of the implantable device (par. 0039). While it is not stated, one of ordinary skill would assume that if the data recorded was not found to be adequate, then the practitioner would adjust the recording triggers accordingly in order to capture the best data possible in the future to suit the needs for each particular patient (par. 0040). While Lade does not disclose that this is done by a processor, attention is directed to *In re*

Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (see MPEP 2144.04). It has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method of Lade by varying the triggers after appraisal of the implantable device in order to record the best and most prevalent data possible in order to provide the best care possible to the patient.

18. Regarding claims 16 and 17, Lade discloses that if the heart rate increases at all, this may be indicative of an arrhythmia, including only 1 extra heart beat (see table 1).

19. Regarding claim 18, Lade discloses that the suspected arrhythmia is confirmed prior to transferring data (par. 0058).

20. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lade in view of Legal Precedent and further in view of Official Notice. Lade, as described above, discloses the applicant's basic invention with the exception of using heart rate variability changes as an indication of arrhythmia. However, the Examiner takes Official Notice that changes in heart rate variability is notoriously well known to those skilled in the art as a strong indicator of cardiac arrhythmia, specifically T-wave alternans. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Lade to incorporate heart rate variability (HRV) as a trigger since it is well known in the art that HRV is an indicator of cardiac arrhythmia.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
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EDB